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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/550,154	09/20/2005	Margaretha Grind	ASZD-P01-022	1056

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MORGAN LEWIS & BOCKIUS LLP
1111 PENNSYLVANIA AVENUE NW
WASHINGTON, DC 20004

EXAMINER	
KHANNA, HEMANT	
ART UNIT	**PAPER NUMBER**
1654	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	03/29/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/550,154	GRIND, MARGARETHA	
	Examiner	Art Unit	
	Hemant Khanna	1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *04 January 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *14,16 and 18-21* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *14, 16, 18-21* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. This office action is in response to Applicant's remarks filed January 04, 2007. The text of those sections of Title 35, U.S. Code not included in this action can be found in the prior Office Action.

Claims 14, 16, 18-21 are pending.

Amended claims 35, and 38 are drawn to an invention that is independent or distinct from the elected invention examined. In light of Applicant's Remarks filed August 11, 2006, election was made without traverse of the invention of Group I encompassed by claims 14, 16, 18-21. Claims 35, and 38 as originally filed were withdrawn from consideration as being drawn to a non-elected invention in the Examiner's action filed September 06, 2006. Accordingly amended claims 35 and 38 are withdrawn from consideration as being drawn to a non-elected invention.

Specification

2. (Withdrawn) Objection to the lack of the title "Brief Description of Drawings" is withdrawn in view of Applicant's amendments to the specification.

Claim Objections

4. (Withdrawn) Objection to claim 19 as containing annotations in the claims is withdrawn in view of Applicant's arguments that point out the definitions of the annotations in the specification.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. (New) Claim 16 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 16 recites the limitation "treatment" in line 1, of claim 16. There is insufficient antecedent basis for this limitation in the claim. Claim 16 depends from claim 14, which recites a therapy method. The above-mentioned limitation is not found among the limitations in claim 14.

Claim Rejections - 35 USC § 102

5. (Maintained) Claim 14, 16, and 18-21 rejected under 35 U.S.C. 102(b) as being anticipated by Gustafsson D. (WO 02/36157) as evidenced by "The Complete Drug Reference" (as cited by the Applicant in the Remarks filed January 04, 2007) and Kralova (Vnitrni Lekarstvi (1963) 8:974-982).

The claims are drawn to a method of administering melagatran and prodrugs thereof to a patient in need of cholesterol-lowering therapy.

Applicant's argue that Gustafsson relates to the use of melagatran and its derivatives in the treatment of ischemic disorders in a patient having or at risk of atrial fibrillation (AF). Applicants contend that the present specification describes the patient population for the claimed therapy as being different from the population utilized by

Gustafsson. Applicant's further argue that AF is distinct from cholesterol-based diseases by pointing to the "The Complete Drug Reference" which indicates differences in drug therapies for the different diseases, with thrombin inhibitors being preferred for patients with ischemic disorders.

Applicant's arguments have been considered but not found persuasive.

The Applicant's arguments are moot in view of Gustafsson's explicit disclosure (page 6, lines 1-10) that low molecular weight thrombin inhibitors, such as a prodrug of melagatran are acceptable for use in cholesterol-lowering therapy, which includes any therapy that results in beneficial modifications of serum profiles of total cholesterol, lipids, lipoproteins and apolipoproteins.

Further evidence that the instantly claimed method of cholesterol-lowering therapy is not unobviously distinct from the method described by Gustafsson is based on a correlation between a therapy for lowering cholesterol in a patient which is associated with lowering the risk of ischemic heart disease described in "The Complete Drug Reference". On page 823, column 3, paragraph 5, "The Complete Drug Reference" describes "Plasma-cholesterol concentrations of 5.2 mmol/litre (200 mg/dL) or less are associated with a low risk of ischaemic heart disease". Additional evidence of the correlation between a patient in need thereof of treatment for "ischemic heart disease" and one having "high cholesterol" is discussed by Kralova who teaches "In 114 patients there was a definite relation between the progressive phase of ischemic heart

disease and high cholesterol (I) level, which seemed to rise not only with the activity but also with the extent of vascular changes (abstract).

Final evidence is based on Applicant's admittance that the instant clinical trial protocol (Example 1) was similar in dosage, compound, and patient population (one having a history of AF and coronary heart disease, page 11, lines 1-20) to the one utilized by Gustafsson to demonstrate the effectiveness of the melagatran prodrug for the treatment of ischemic disorders.

Rejection is maintained.

Conclusion

6. No claims are allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Hemant Khanna whose telephone number is (571) 272-9045. The examiner can normally be reached on Monday through Friday, 7:30 am-4:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang can be reached on (571) 272-0562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Hemant Khanna Ph. D.
March 21, 2007

Cecilia J. Tsang
Supervisory Patent Examiner
Technology Center 1600